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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

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Application No.: 08/192,861 Group: 1806  
Filed: February 4, 1994 Examiner: J. Lucas  
For: METHODS OF TREATING TNF $\alpha$ -MEDIATED DISEASE  
USING CHIMERIC ANTI-TNF ANTIBODIES

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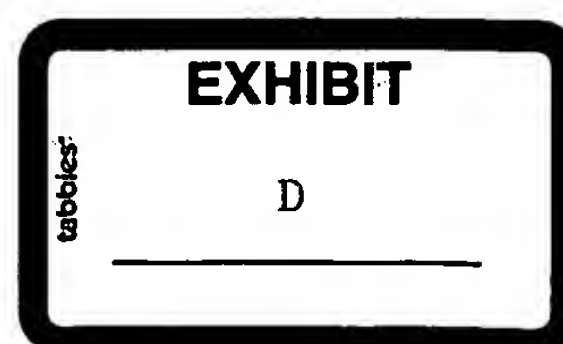
AMENDMENT

Assistant Commissioner for Patents  
Washington, D.C. 20231

Sir:

This Amendment is being filed in response to the Office Action mailed from the U.S. Patent and Trademark Office on January 23, 1998 in the above-identified application.

A three-month extension of time to respond to the Office Action is respectfully requested. A Petition for a three-month extension of time is being filed concurrently together with the appropriate fee.



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specification (e.g., page 61, lines 14-37 and page 62, lines 9-16) are the subject matter for a method of treatment in newly added Claims 125 and 126. Accordingly, withdrawal of the rejection and reconsideration are respectfully requested.

Rejection of Claim 112 Under 35 U.S.C. § 112, Second Paragraph

Claim 112 has been rejected under 35 U.S.C. § 112, second paragraph as being indefinite for failing to particularly point out and distinctly claim the cA2 antibody. The Examiner insists that the cA2 antibody be referred to by an ATCC accession number. Applicants strongly disagree that the designation cA2 is indefinite and that deposition of the antibody be required to satisfy 35 U.S.C. § 112, second paragraph.

The Examiner suggests that Applicants deposit the antibody or refer to the cA2 antibody by an amino acid or DNA sequence. Respectfully, Applicants disagree with the Examiner's static position in insisting on ATCC deposition of the antibody and on refusing to accept Applicants designation of a chimeric antibody as "cA2 antibody", which is extensively described in the specification. (See, for example, EXAMPLE I page 75, lines 16-34, and page 76, lines 1-30; EXAMPLE II page 77, lines 1-37, and page 78 lines 1-35; EXAMPLE V page 80, lines 19-34; EXAMPLE VII page 83, lines 29-35, and page 84 lines 1-17; EXAMPLE X page 85, lines 29-36, and page 86 lines 1-36; EXAMPLE XVI page 101, lines 30-36, and page 102, lines 1-35).

As discussed in several previous responses in this case, the cA2 antibody has not been deposited with the ATCC, and therefore, it has no ATCC accession number. As stated in the Manual of Patent Examining Procedure, § 2172.01, "[a] fundamental principle contained in 35 U.S.C. § 112, Second Paragraph, is that Applicants are their own lexicographer." In addition, "a claim may not be rejected solely because of the type of language used

to define the subject matter for which the patent protection is sought" § 2173.01. Applicants, in acting as their own lexicographers, created the designation cA2 for the specific chimeric anti-TNF $\alpha$  antibody disclosed in the application. The specification discloses activities of the antibody and the DNA (SEQ ID NOS: 2-5) and amino acid sequences of the heavy and light chain variable and constant regions of the cA2 monoclonal antibody in Figures 16A and 16B. The specification thereby defines the antibody and enables a person of ordinary skill in the art to produce cA2 and/or screen antibodies which have the same or similar properties without undue experimentation.

The term "cA2" must be read in light of the specification, not independently from the specification as the Examiner chooses to do in this application. The Examiner implies that the term may be used by other laboratories. Even if this were true, although highly unlikely, that subsequent use does not alter the definition of the terms provided in this application. That "factor" or possibility applies to all terms employed in claims, even routine or ordinary words.

Furthermore, in two related applications, Serial No. 08/192,102, now issued U.S. Patent No. 5,656,272, and Serial No. 08/324,799, now issued U.S. Patent No. 5,698,195, claims drawn to cA2 were granted by the Examiner. Frankly, Applicants do not understand why the Examiner allowed two patents reciting cA2 in the claims and his refusal to accept the term cA2 in Claim 112 of the instant application. Applicants are highly concerned with the confusing record the Examiner is creating. Accordingly, withdrawal of the rejection of Claim 112 is respectfully requested.